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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,456	11/14/2001	Maurice Zauderer	1821.0070004/EKS/EJH/TAC	6770

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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8/19

Office Action Summary	Application No.	Applicant(s)	
	09/987,456	ZAUDERER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *84-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *84-131* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

SUBSTITUTE RESTRICTION

1. The Response to the Restriction Requirement filed on February 13, 2004, is acknowledged.

2. Upon further review of Applicants' newly added claims (i.e., claims 84-131) and in view of Applicants' deletion of all previously pending claims (i.e., claims 1-83), all previous restriction and election of species requirements are hereby withdrawn and a new substitute restriction and/or election of species is now required (see below).

Election/Restriction

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 84-122, 127-131 drawn to a method for selecting and/or producing polynucleotides which encode an antigen-specific immunoglobulin molecule, classified variously in class 435, subclass 6, 7.1, 7.2, DIG 6, 47.

II. Claim 123, drawn to an antibody, classified in class 530, subclass 387.1+.

III. Claim 124, drawn to a composition, classified variously in class 424, subclass 464+, class 424, and subclass 130.1+.

IV. Claim 125, drawn to a host cell produced by the method of claim 94, classified variously in class 435, subclass 325+, 455+.

II. Claim 126, drawn to a kit, classified variously in class 436, subclass 808; class 435, subclass 975.

4. The inventions are distinct, each from the other because of the following reasons:

5. Groups I-V represent separate and patentably distinct inventions. Groups I is drawn to a method while Groups II-V are drawn to different products and/or kits (i.e., e.g., which are directed to different purposes, use different materials, recite different method or process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing

6. Groups II-IV represent patentably distinct products. Groups II-IV represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group IV requires "a hostcell", which is not required by the other Groups. Likewise, Group II requires a "carrier", which is not required by the other groups. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups II-IV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. In addition, Groups II-IV and V represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group V refers to a plurality of articles grouped together to form a "kit", whereas Groups II-IV refers to only a single article or an article with a pharmaceutically acceptable carrier. These Groups also have different purposes e.g., the kit can be used for screening whereas the pharmaceutical composition is used for treating health problems. Therefore, Groups II-V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

8. Finally, if the applicant argues that Groups I and any Groups II-IV are somehow related as process of making and product made, the inventions can be considered to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be made by another materially different process e.g., transgenic mice, bacteriophage display, virus without tri-molecular recombination, solid-phase synthesis, computer design. Furthermore, (1) the process can be used to make materially different products i.e., the products listed in Groups II-V.

9. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require

completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

10. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-V. Election is required as follows.

11. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 84 is generic.

Subgroup 1: Species of host cells (e.g., see claim 84)

Applicant must elect, for the purposes of search, a ***single species*** of host cells e.g., HeLa cells (see specification page 8, paragraph 1). Please also indicate whether the elected host cells are permissive for the production of infectious viral particles (e.g., permissive for vaccinia virus infectivity).

Subgroup 2: Species of second library of polynucleotides ability to infect (e.g., see claim 85)

A. Second library is capable of producing infectious particles
B. Second library is NOT capable of producing infectious particles

Applicant must elect, for the purposes of search a ***single species*** from the list above i.e., A or B.

Subgroup 3: Species of repeating steps (f)-(j) (e.g., see claims 86-87)

Applicant must elect, for the purposes of search, a ***single species*** of repeating steps (f)-(j) i.e., 0, 1, 2, 3, etc.

Subgroup 4: Species of repeating steps (p)-(t) (e.g., see claim 91)

Applicant must elect, for the purposes of search, a ***single species*** of repeating steps (p)-(t) i.e., 0, 1, 2, 3, etc.

Subgroup 5: Species of immunoglobulin (e.g., see claim 84)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin e.g., human. Please also indicate whether the species is **secreted** or membrane bound. Please also indicate whether immunoglobulin is IgM, IgG, etc (e.g., see figure 13).

Subgroup 6: Species of first and second library construction (e.g., see claim 84)

Applicant must elect, for the purposes of search, a ***single species*** of first library construction and second library construction e.g., eukaryotic virus vector. Please specify the actual virus (e.g., vaccinia virus vector). Please also indicate whether the virus is attenuated (e.g., see claim 105). Please also indicate whether the virus is deficient in D4R synthesis (e.g., see claim 106).

Subgroup 7: Species of promoter (e.g., see claims 84, 100-101)

Applicant must elect, for the purposes of search, a ***single species*** of promoter e.g., vaccinia virus p7.5 promoter. Please also indicate whether the promoter is a synthetic early/late promoter and whether the promoter is constitutive.

Subgroup 8: Species of transcriptional control region (e.g., see claims 104-105)

Applicant must elect, for the purposes of search, a ***single species*** of transcriptional control region e.g., whether region contains T7 RNA polymerase or termination region.

Subgroup 9: Species of vaccina virus genome (e.g., see claims 84 and 108)

Applicant must elect, for the purposes of search, a ***single species*** of vaccina vius genome e.g., v7.5/tk virus genome. Please indicate for both fist and second libraries (e.g., see claim 111).

Subgroup 10: Species of viral fragment generation (e.g., see claims 109)

Applicant must elect, for the purposes of search, a ***single species*** of viral fragment generation e.g., NotI restriction site. Please indicate for both first and second libraries (e.g., see claim 112).

Subgroup 11: Species of repeating steps (a)-(d) (e.g., see claims 115-116)

Applicant must elect, for the purposes of search, a ***single species*** of repeating steps (a)-(d) i.e., 0, 1, 2, 3, etc.

Subgroup 12: Species of repeating steps (a)-(d) (e.g., see claims 119-120)

Applicant must elect, for the purposes of search, a ***single species*** of repeating steps (a)-(d) i.e., 0, 1, 2, 3, etc.

Subgroup 13: Species of detection (e.g., see claim 121)

Applicant must elect, for the purposes of search, a ***single species*** of detection e.g., ELISA.

Subgroup 14: Species of transfer plasmids (e.g., see claim 107)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., specify type including whether or not it has a vaccina promoter and also any relevant non essetial virus sequences e.g., poxvirus.

Subgroup 15: Species of signal peptide (e.g., see claim 84)

Applicant must elect, for the purposes of search, a ***single species*** of signal peptide (e.g., -19 to –2 of the kappa light chain, see specification, bottom of page 106).

12. If applicant elects the invention of Groups II-III, applicant is required to elect from the following patentably distinct species. Claims 123 is generic for Group II and 123 is generic for Group III.

Subgroup 1: Species antibody (e.g., see claim 123)

Applicant must elect, for the purposes of search, a ***single species*** of antibody i.e., provide Sequence ID NO to which Applicant will be restricted to as a group. Please note that each antibody constitutes its own group and is not a "species election" for purposes of search.

Subgroup 2: Species of carrier (e.g., see claim 124)

If Applicant elects Group V, Applicant must further elect a ***single species*** of carrier. Please note that Applicants only need to elect a carrier if Group III is chosen.

13. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 50 is generic.

Subgroup 1: Species host cell (e.g., see claims 50, 51)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., COS.

14. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 126 is generic.

Subgroup 1: Species host cell (e.g., see claim 126)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., COS.

Subgroup 2: Species first library (e.g., see claim 126)

Applicant must elect, for the purposes of search, a ***single species*** of first library.

Subgroup 3: Species first immunoglobulin subunit (e.g., see claim 126)

Applicant must elect, for the purposes of search, a ***single species*** of first immunoglobulin subunit.

Subgroup 4: Species signal peptide (e.g., see claim 126)

Applicant must elect, for the purposes of search, a ***single species*** of signal peptide.

Subgroup 5: Species virus particles (e.g., see claim 126)

Applicant must elect, for the purposes of search, a ***single species*** of virus particles.

15. **Please Note:** Applicants must disclose which claims read on the elected species ***in toto*** (see paragraphs 19 and 20 below).

16. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

17. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

19. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable***

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

22. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the

merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

24. Finally, Applicant is reminded that where applicant elects claims directed to a product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the

process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
April 21, 2004

BENNETT CELSA
PRIMARY EXAMINER